EXHIBIT 154

E0567.1

From: Hudson, Denise
Sent: Wednesday, November 16, 2011 4:48 PM
To: Hernandez, Tracey; Green, Jeff; Bishop, Mike; Haskins, Dennis; Burke, Joe; Cook, Steve; Connell, Jill; Richardson, Margaret; Baker, Goff
Subject: RE: DEA Inspection Wrap-Up in Charlotte (11/15/2011)

Wow! Tracey, thank you for the thorough review of the DEA visit and for managing the inspection so well. Mike, I appreciate the good work you did in providing clear and meaningful information to the DEA. Dennis, as Tracey said, good work on the follow ups related to installing good equipment and hiring good management staff.

Interesting new thinking by the DEA – but it makes sense. Once you get some of the immediate next steps completed, I would appreciate understanding what you think the broader implications of this feedback are for us and how we should plan to address management and reconciliation of controlled substances in the future.

Denise

From: Hernandez, Tracey
Sent: Wednesday, November 16, 2011 10:17 AM
To: Green, Jeff; Bishop, Mike; Haskins, Dennis; Burke, Joe; Cook, Steve; Connell, Jill; Richardson, Margaret; Hudson, Denise; Baker, Goff
Subject: FW: DEA Inspection Wrap-Up in Charlotte (11/15/2011)

All-

Yesterday, DEA Investigator Stephanie Evans and Group Supervisor Brian Reise arrived at the Charlotte facility (3700 Woodpark Blvd) at approximately 11:00 am. DEA had contacted us prior so we were aware that they would be on-site. The purpose of their visit was two-fold:

(1) They wanted to close out a DEA inspection of the 3241 Woodpark Manufacturing Registration which began over a year ago (May 2010), and obtain samples as part of their routine inspection process.
(2) They wanted to speak to us about the recent employee theft incident that had occurred at the 3241 building

Prior to the inspection, Mike Bishop and I reviewed some of the documents that had been provided to the investigator during the inspection. It became obvious that he had gone to extensive lengths to assure the investigator understood the process and interpreted it correctly. He had actually mimicked their computation charts, ran reports and made notes on the copies given to them that would clearly depict our active ingredient, WIP and finished goods accountability (nice job Mike)! With the exception of Meperidine, all products had balanced within +/- 2%, which has historically been DEA's requirement (although that % is not documented anywhere in the regulations). Internally, we had concerns about how to capture meperidine quantities lost in the manufacturing process (due to the small batch size much can be lost through the filtering system – some is captured but not all). On paper, it appeared that would be DEA's only concern.

Upon DEA's arrival, they were escorted to a conference room with Jeff Green, Mike Bishop, Dennis Haskins, John Kaiser (joined slightly after the start at the request of Jeff) and myself. Group Supervisor Reise asked to discuss the employee theft and I asked that they save that until the end for discussion with Dennis and I (they agreed). He then began discussing the discrepancies generally and we asked if there was a specific product he was concerned about. He indicated he was concerned about all of them and that he believes manufacturers have it all wrong; they should not be seeking to have accountability within a specified range, they should be reconciling with zero discrepancy. A discussion

ensued about all of the ways that a manufacturer could lose product (API received from manufacturer was less than stated, product film sticks to bags despite shaking, dust in room/some captured but some lost in wet wash, filters, crushed tablets, theoretical tablet weight calculation, etc.). At first, it appeared that Mr. Reise was not familiar with the manufacturing process. But, after the discussion, it was obvious he was aware and understood that some loss would occur but wanted more solid proof and measuring done of that loss, rather than assuming that it occurred in those places. We talked about adjustments that might be made in the system at the end of an API batch, about including plastic bags in with controlled substance waste when they contain film (which he indicated was required) and about looking at better ways to capture dust or measure the quantity lost in a wet wash. We also talked about assay testing and about using the actual tablet weight in calculations where we currently use a theoretical tablet weight (waste). However, Mr. Reise cautioned that even the actual tablet weight is theoretical as we are not physically counting every tablet (he noted that some manufacturers have gone to that extent and have purchased tablet counters).

He noted that he was concerned because even though we may have only lost .15% for one of the products (when calculated using all of the batches manufactured during their audit period), that .15% equated to 64 kgs of raw material. He gave several other examples. He went on to say that manufacturers are making larger batch sizes and greater quantities of controlled product than in years past. DEA is seeing a much higher rate of prescription drug abuse and diversion as compared to illicit drugs now. Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations. He stated that we have the public's trust in our hands and we need to be sure we are staying ahead of the curve by monitoring current diversion trends and tightening our processes. He indicated that the thefts we've experienced prove we need to do a better job. He ended by saying he was not going to give us a violation letter at this time but that they did expect us to take action to review and enhance our processes, as they would be back to check on our actions (no timeline given). We assured him that we would do that.

The investigators then filled out a Receipt for Samples form and were supplied with the following retain samples:

- One bottle of 100, Hydrocodone/APAP 2.5/500, Lot #C0521111A
- One bottle of 100, Propoxyphene/Napsylate 100/650, Lot #C1381010B

They also requested a label and package insert for each product (which they received) and several additional items regarding our procedures for securing punches & dyes and the tooling and equipment used to manufacture the above batches (this information will be sent to them this week).

DEA also asked about the Manufacturing license we had submitted for the 3700 Woodpark address and the fact that the application had included Schedule I. They were concerned about that. We told them that the license application had been submitted prior to my coming to the company and that we had since decided to apply for Analytical Laboratory licenses which is where the Schedule I drug (codeine-n-oxide) would be purchased, as a reference standard. They were happy to hear we were not looking to manufacture the product and indicated that they would remove it from the Manufacturer application. We agreed.

DEA then met with Dennis and I to discuss the recent employee theft. DEA was interested in knowing the employment status of the individuals and more details about the corrective actions we were putting in place. Dennis went over the physical security aspects (additional cameras, card access, etc.). While DEA was impressed with the amount of equipment being installed, they also commented that cameras did not take the place of people/supervision. Dennis then talked to them about his recent hire of a Security Supervisor for the Charlotte facility. DEA had been extremely impressed when Dennis told them earlier that he had hired Ernie Kirchin. Both individuals from DEA knew Ernie and had worked with him before. They discussed his accomplishments at length during the time Dennis and I were with them and definitely appeared to be comforted by the addition (nice job Dennis)! We also told DEA about the new procedures, the General Policy for Working with Controlled Products and the Controlled Substance Coordinator/Manager roles we will be implementing shortly. Again, they were very happy to see that there would be additional eyes on the controlled substance operation.

We discussed how DEA's thinking in regards to accountability had changed over the years and how similar it was to the policy change that occurred a couple of years ago with Suspicious Order Monitoring(SOMS). DEA then spoke about SOMS at length and also discussed the need to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits. This is not something we are currently doing and another item we will need to work on improving.

At that point, DEA left the facility after staying for approximately two and a half hours.

In discussions with Jeff and Mike after the inspection, there are several action items we took away:

After the Thanksgiving holiday Tracey will schedule a meeting with representatives from both Huntsville Tablets and Charlotte to review our controlled substance manufacturing processes and the areas mentioned during the inspection. Some of the information we discussed is already being captured by both sites but there is not necessarily a comparison between each individual batch record to those items, as part of the reconciliation process. We felt that the recommendations given by Group Supervisor Reise were ones that should be implemented across the board and that both sites could benefit by reviewing best practices in these areas. Later down the line we will also look to include Liquids but felt it best to concentrate on tablet manufacturing first.

Jeff and Mike will do some preliminary investigating in Charlotte to prepare for that teleconference. They will gather more detailed data on the vacuum and filter process, the capturing of assay data and adjustments made to API quantities for their controlled products. I will reach out to Tablets to do the same so that we have some preliminary data to look at when we all get together.

If you should have any questions, please do not hesitate to call me.

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